UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,586	11/30/2000	Michael Kock	49100	5846

26474 7590 10/13/2009

NOVAK DRUCE DELUCA + QUIGG LLP
1300 EYE STREET NW
SUITE 1000 WEST TOWER
WASHINGTON, DC 20005

EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/701,586	KOCK ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 33-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *61* is/are allowed.

6)☒ Claim(s) *1-3 and 33-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claims 1, 3, 34-47, 51-60, and the addition of new claim 61, in the paper of 6/16/2009, is acknowledged.

Claims 1-3 and 33-61 are at issue and are present for examination.

Applicants' arguments filed on 6/16/2009, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claim 1 is objected to because of the following informalities: Newly amended claim 1 recites "at least 85% identity with human PARP2 (SEQ ID NO:2)" This should be "at least 85% sequence identity with human PARP2 (SEQ ID NO:2)".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-3 and 33-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, on the basis of

lack of support for the limitation "at least 95% homologous to human PARP2 (SEQ ID NO:2)" is withdrawn based upon applicants amendment of the claims.

Claims 1-3 and 33-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a poly(ADP-ribose) polymerase (PARP) homolog comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any poly(ADP-ribose) polymerase (PARP) homolog with at least 85% identity with human PARP2 (SEQ ID NO:2), and has a functional NAD^+ binding domain with the sequence $PX_n(S/T)GX_3GKGIYFA$, wherein n is an integral value from 1 to 5, and lacks a zinc finger motif with the sequence $CX_2CX_MHX_2C$, wherein M is 28 or 30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 1-3 and 33-60. In response to the rejection applicants have amended claims 1, 3, 34-47, 51-60 and argue the rejection as it applies to the newly amended/added claims.

Applicants note that they have amended independent claims 1, 38 and 47 to recite "a PARP homologue having at least 85% identity with human PARP2 (SEQ ID NO: 2)." and submit that in view of the direction provided by the instant disclosure and the knowledge available to an ordinarily skilled artisan at the time the invention was made, such artisan would be sufficiently enabled to make and use the invention without

undue experimentation. Applicant's further note that the reference, Pearson et al. "Improved Tools for Biological Sequence Comparison," which sets forth that the FASTA program, described at page 19 of the originally filed specification, was a well known and commonly used algorithm for purposes of searching sequence databases, comparing protein and DNA sequences, and calculating percent identity.

Applicant's complete argument is acknowledged and has been carefully considered, however, is not found persuasive on for the reasons previously made of record and repeated herein.

Applicants argument continues to be found non-persuasive on the basis that the breadth of applicants claimed genus continues to be broad enough that while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as encompassed by applicants claims and eluded to in applicants arguments requires that one of ordinary skill in the art know or be provided with sufficient guidance for the selection of which of the infinite number of variants have the claimed property. This continues to be true in light of the breadth of the claims that are merely limited to those polypeptides having 85% identity to the human PARP2 polypeptide. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the

experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting poly(ADP-ribose) polymerase activity; (B) the general tolerance of poly(ADP-ribose) polymerases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a poly(ADP-ribose) polymerase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. While applicants have pointed to the Pearson et al. reference and applicants submit that its teachings include a well known and commonly used algorithm for purposes of searching sequence databases, comparing protein and DNA sequences, and calculating percent identity, this does not account for the lack of sufficient guidance to design and use the extreme breadth of mutant and variant protein homologs encompassed by applicants claims.

Thus it continues that because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the poly(ADP-ribose) polymerase activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed poly(ADP-ribose) polymerase functional equivalents. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Of note, applicants have not commented on or clearly responded to applicants previously made reference to "at least 85% or 95% homologous" is not necessarily limited to amino acid sequence homology and may be interpreted as "functional homology", an issue which does not help applicants meet the requirements of 112 first paragraph.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgh
10/9/2009

/Richard G Hutson/
Primary Examiner, Art Unit 1652